(3) *For products containing any combination identified in §333.320.* ''Apply to affected areas only. Do not use on broken skin or apply to large areas of the body.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) ''Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day.''

(2) The directions described in paragraph (d)(1) of this section are intended for products that are applied and left on the skin. Other products, such as soaps or masks, may be applied and removed and should have appropriate directions.

(3) *Optional directions.* In addition to the required directions in paragraphs (d)(1) and (d)(2) of this section, the product may contain the following optional labeling: ''*Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated: (select one of the following: 'elsewhere on this label,' 'above,' or 'below.')''

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

PART 335—ANTIDIARRHEAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 68 FR 18881, April 17, 2003, unless otherwise noted.

EFFECTIVE DATE NOTE: At 68 FR 18881, April 17, 2003, Part 335 was added, effective April 19, 2004.

Subpart A—General Provisions

§335.1 Scope.

(a) An over-the-counter antidiarrheal drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in §330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§335.3 Definitions.

As used in this part:

(a) *Antidiarrheal.* A drug that can be shown by objective measurement to treat or control (stop) the symptoms of diarrhea.

(b) *Diarrhea.* A condition characterized by increased frequency of loose, watery stools (three or more daily) during a limited period (24 to 48 hours), usually with no identifiable cause.

Subpart B—Active Ingredients

§335.10 Antidiarrheal active ingredients.

The active ingredient of the product consists of any one of the following when used within the dosage limits established for each ingredient in §335.50(d):

(a) Bismuth subsalicylate.

(b) Kaolin.

Subpart C—Labeling

§335.50 Labeling of antidiarrheal drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product either as an ''antidiarrheal'' or ''for diarrhea.''

(b) *Indications.* The labeling of the product states, under the heading